UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,149	10/20/2003	Miri Seiberg	3282-P02872US04	6375

110 7590 06/29/2010

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,149	SEIBERG ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *5-8,10-12,14-16,21-24,26-28 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,13,17-20,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 04/07/10, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 9, 13, 17-20, 25, and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan (US 4,906,457, see IDS filed 07/12/04) in view of Maeda et al (JP 07010772, see IDS filed 07/12/04).

Applicants assert BBI is unique from Kunitz-type soybean trypsin inhibitors and '457 teaches the use of trypsin family of protease inhibitors, specifically exemplifying soybean derived BBI. Further, Applicants assert '457 only teaches potato inhibitor 1 family of proteases which inhibit chymotrypsin, therefore the patent only teaches the anti-cancer properties of chymotrypsin inhibitors. Applicants also assert the article by Gennedy, Amer. J Clin Ntr (1998) and US 5,961,980, disclose ten years after the '457 patent, the general understanding in the art was that chymotrypsin inhibitors were responsible for the anti-cancer properties of soy. Applicants then assert the '772 application only discloses the Kunitz-type soybean trypsin inhibitor suppresses increased inflammation edema. Applicants conclude that non-denature Kunitz-type

soybean trypsin inhibitor shows superior results compared to BBI and denatured soy product.

Examiner disagrees. First, Examiner notes disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Even so, '457 specifically claims a topical composition for reducing the risk of skin cancer by topically applying a protease enzyme inhibitors of the trypsin class of proteases (claim 17). Among the Markush grouping is also BBIs and protease enzyme inhibitors of the potato inhibitor 1 family. Thus, the claims are not limited to a specific mechanism as asserted by Applicant by appears to be directed to a broader genus of protease enzyme inhibitors, including protease enzyme inhibitors of the trypsin class.

Second, with regards to the teaching away reference, the cited reference appears to discuss the presence of BBIC in soybeans only in BBI. As the article is directed to BBI and BBIC, such disclosure does not suggest that BBIC is the only active agent, but that it is presumed to be the active in the BBI compounds. Additionally, with regards to the '980 patent cited, Examiner notes the comparison is based on the inhibition of H_2O_2 formation. But the disclosure is only based on a single potential mechanism which may not be the same mechanism of the primary reference. Thus, such a showing is not relevant where the primary reference specifically includes protease enzyme inhibitors of the trypsin class of proteases.

Finally, with regards to the unexpected results, such results are not sufficient to show unexpected results. Specifically, at week 21, the values between no treatment,

STI, and BBI, are not sufficient to determine the unexpectedness of the results where the error is so high that the ranges all overlap. Finally, Examiner notes the difference in tumor volume per mouse between no treatment and STI without taking error rates into consideration is only a few mm^3 which does not suggest an unexpected result, especially as water along produces a significantly lower tumor volume per mouse and the topical STI preparation would reasonably be expected to have an aqueous carrier.

Claims 1-4, 9, 13, 17-20, 25, and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jolles et al (Br J Radiol, 39 (1966) pp 12-18) in view of Ryan (US 4,906,457, see IDS filed 07/12/04).

Applicants assert the experiments of Jolles are directed to early tissue changes after exposure to ionization radiation where the inflammatory reaction plays a major role and the method fails to teach capillary leakage is associated with or is related to the risk of cancer development. Applicants also assert Jolles does not teach administration of a singular soybean product. Further, Applicants assert Jolles expressly teaches away where Jolles concludes that trypsin itself is not the mediator. Applicants also assert Jolles does not teach topical administration and '457 does not cure this deficiency.

Examiner disagrees. First, Examiner notes the instant claims are directed to a method which reduces the risk of cutaneous tumor development in skin cells that are not yet damaged by UV radiation by topically administering a composition which comprises a non-denatured, Kunitz-type soybean trypsin inhibitor. Thus, the active

steps are applying a composition which comprises a non-denatured, Kunitz-type soybean trypsin inhibitor to skin which is not yet UV damaged. Thus, where Jolles discloses administration of STBI to rabbits prior to exposure, the active steps appear to be met, with the exception of topical application. It was noted that various compounds tested were administered via differing routes, including intra-venous and topical (see pgs 14-15 Tables II and III).

Second, the instant claims are not limited to a singular soybean product. Instead, the transition phrase "comprising" is an open transition phrase which allows the addition of other components. Even so, the substance disclosed in Jolles is explicitly soya bean trypsin inhibitor, which appears to be a synonym for non-denatured, Kunitz-type soybean trypsin inhibitor as explained in the Office action dated 1/20/10 and incorporated herein by reference.

Third, while Jolles teaches trypsin itself is not the mediator is not relevant where it is taught the protease antagonists which include soya bean trypsin inhibitors eliminate the response. As such, the response is likely mediated through a proteolytic enzyme system and therefore soya bean trypsin inhibitors would still produce the desired proteolytic enzyme effect.

Finally, as discussed above, Ryan claims application of soybean trypsin inhibitors topically to reduce the risk of skin cancers. Thus, it would be obvious to modify the administration of Jolles to other methods known in the art to impart the anticancer protective effect, as taught by Ryan.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612